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10/043,539	01/11/2002	Ambrose L. Cheung	DC-0199	7285

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,539	CHEUNG ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Letter dated September 28, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-31 are pending.

Prosecution Reopened

1. In light of the letter mailed to Applicant on September 28, 2005 identifying an issue under 37 CFR 1.313(b), the letter having been signed by George C. Elliott, Director of Technology Center 1600, prosecution is herein reopened.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 30-31 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 5,587,288. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

4. the allowed species of invention anticipates the instantly claimed genus of SarR analogs.

The allowed species of SarR analog, specifically a species of SarA that shares amino acid sequence similarity with SarR; serves to bind SarA promoters to repress transcription of collagen adhesion, protein A and several other genes encoding extracellular proteases which are known to be Staphylococcal virulence factors as well as would form a heterodimer with SarA of a different

amino acid sequence as the allowed SarA because SarA is known to form dimers in the native host bacteria.

The allowed species anticipates the instantly claimed genus of SarR analogs based upon the functional characteristics recited in the claims. The claimed compound analogs not having been so claimed to be structurally distinguished from the allowed species of SarR analog.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. At page 30, the phase www.tiger.org is recited. This phrase must be removed.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 30-31 are directed to compounds that have not been isolated and purified to show the "hand of man" and are therefore directed to non-statutory subject matter. This rejection could be obviated by amending the claims to recite the phrase ----isolated and purified----.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Please Note: The examiner is reading the scope of what is now claimed in light of the various definitions set forth in the instant Specification.

The instant Specification defines the SarR analogs to include SEQ ID NO 1, analogs of SEQ ID NO 1, homologs of SEQ ID NO 1 (see Instant Specification page 12, third paragraph on page), mutant polypeptides encoded by mutant sarR genes (see Instant Specification, page 5, last paragraph), wherein the homologs are compounds that "possess a "common evolutionary origin" including proteins from superfamilies and homologous proteins from different species. Such proteins have sequence homology as reflected by their high degree of sequence similarity (see Instant Specification page 10, last paragraph), as well as applies to "bacteria having significant sequence, structural or functional homology to the sarR gene or SarR protein" (see Instant Specification page 11, last few lines of first paragraph on page). Additionally, at page 13 of the Instant Specification the SarR analogs are defined to be "in the form of small molecule compounds which alter the functionings of a microbial sarA expression", the small molecules being obtainable by screening a random peptide library or chemical library (see Instant Specification , page 16, paragraph 2).

9. Claims 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the *written description* requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instantly claimed invention is directed to compositions and methods that utilize SarR analogs, the SarR analogs only being functionally defined in the claims to evidence the ability to form heterodimers with SarA (Instant claim 28, 30-31) or bind to an SarA promoter to inhibit virulence determinant expression (instant claim 29-31) which encompass mutant genes and proteins of SarR and small molecules that mimic the functional characteristics of the mutant SarR genes or proteins. While the instant Specification has disclosed SEQ ID Nos 1 and 2, a single nucleic acid that encodes a Staphylococcus aureus SarR protein, the Specification has not described through written description the highly variable genus of analog SarR genes, analog SarR polypeptides and functional equivalents of theses in the form of small molecules.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the nucleic acids and polypeptide encoded by SEQ ID NO: 1 or 2, and polynucleotides present is specific strains of S.epidermidis, haemolyticus and saprophyticus (Figures 3 A-d and 6) the skilled artisan cannot envision the detailed structure of what is encompassed by the SarR analogs that includes mutant, homolog, analog genes and proteins from any source or species of bacteria, as well as small molecule functional equivalents of the

SarR analog and mutant genes and proteins.

Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The actual product itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. A precise definition, such as by structure, formula, chemical name, and physical properties, correlated with function, not a mere wish or plan for obtaining the claimed chemical invention.

However, no disclosure, beyond the mere mention of possible sources of small molecules for future screening of SarR analogs could be found in the instant specification (see Instant Specificaiton page 16, paragraph 4). The Specificaiton all teaches that what is now claimed is a very large number of potential molecules which would includes over 60 million analogs which pose problems in handing and screening (see instant Specification, page 14, paragraph 2).

No specific guidance could be found for where or how many mutations should be introduced into an SarR analog gene coding sequence to produce the desired functional SarR protein in order to obtain or maintain the recited functional characteristics now claimed. There is insufficient guidance and too few species disclosed to support the hyper variable genus of

compounds claimed based upon function only, without a defined structure to support the generic claims as provided by the Written Description guidelines. Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115). Therefore the claimed genus compounds of claims 30-31 have not been described, the compounds have not been so described in such a way that Applicant was in possession of a genus SarR analogs, other than the species represented by SEQ ID NO 1 and 2, and proteins encoded by the specific sequences shown in Figure 3.

10. Claims 30 and 31 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to SarR protein from Staphylococcus aureus, epidermidis, haemolyticus and saprophyticus. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The claims broadly recite any compound that may evidence any number of changes in the amino acid sequence of the SarR protein disclosed in the instant Specification. **Any** change in the amino acid sequence of a SarR protein is being claimed , but **no** specific location for where the deletion, substitution or insertion or any combination thereof within the encoded protein are recited, any deletion, substitution, insertion or inversion which would result is being claimed.

Thomas E. Creighton, in his book, "Proteins: Structures and Molecular Properties, 1984",(pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to

have lower stabilities due to any of several causes:

1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge;

2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a Proline residue, which must distort the alpha-helix;

3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book "Protein structure: A Practical Approach, 1989;pages 184-186" teaches that present day site directed mutagenesis of a gene allows any amino acid in a protein sequence to be changed to any other, as well as introducing deletions and insertions. The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in "Protein Stability and Stabilization through Protein Engineering, 1991" (chapter 7, page 197, second paragraph) adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

Changes in the amino acid sequence which would result in the substitution of **any** amino acid in **any** location within the SarR protein would not predictably result in a stable molecule. The specification teaches the modification of side chains and states that natural or unnatural amino acids and/or their derivatives can be incorporated into the peptide during peptide synthesis and the use of cross linkers and other methods which impose conformational constraint on the

peptides or their analogs can be used. Specific amino acids in specific locations which result in stable mutations are not taught. The disclosure does not provide guidance on how any amino acid can be deleted, substituted or inserted or any combination thereof per protein for the production a stable SarR protein with the required function al characteristics nor does the specification provide guidance on how any location can be used to produce a stable protein. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which deletions, substitutions or insertions or any combination thereof would result in the desired stable, active synthetic peptide that would form a heterodimer with a SarA protein or bind to an SarA promoter or fragment thereof. Accordingly, one of skill in the art would be required to perform undue experimentation to use any amino acid at any location to produce the desired SarR analog protein that would inhibit expression of Staphylococcal virulence determinants. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

10. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 29 recite the phrase "or fragment thereof" in the "contacting" and "determining" steps of the claimed method. The fragment recited in the claim being a fragment of a SarA promoter but is not required to be a functional fragment that also evidences promoter activity, as the fragment may be any fragment of a SarA promoter. This recitation of the term "fragment"

includes a single nucleotide. The claimed fragments are not identified by any specific structure and are not required to evidence any specific biological function as now claimed.

No single nucleotide fragment or fragments have been described in the instant Specification, nor are any single nucleotide fragments well known in the art to function as a promoter which would also bind to an SarR analog in such a way as to inhibit expression of virulence determinants of Staphylococcus. Therefore, the method of claim 29 is not enabled for the utilization of any fragment of a SarA promoter sequence to identify lead compounds that would serve to inhibit the expression of virulence determinants. See In re Mayhew 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 29, 30-31 are rejected under 35 U.S.C. 102(a) as being anticipated by Tegmark et al (2000).

13. Tegmark et al disclose the instantly claimed invention directed to:

(Instant claims 30-31) a compound that inherently would function as a Staphylococcal accessory regulatory (SarR) analog, wherein Tegmark et al isolated the SarR protein analog from S. aureus and named it "P13" .

The compound of Tegmark et al is not described based upon its biological function, ie. being an SarR analog of S.epidermidis and S.haemoyticus SarR proteins (evidence of difference in protein sequence, but still being an SarR protein is presented in Swiss-Prot accession number Q4L8F0 and Q5HLV6)

but the compound of Tegmark et al evidenced an N-terminal amino acid sequence that shares 100% amino acid sequence identity with a species of SarR protein disclosed in the instant Application (see page 399, col. 2, first paragraph, and Fig. 1, arrow pointing to protein in gel) .

Based upon the identical amino acid structural characteristics, the biological function and effects of the "P13" protein define the disclosed "P13" protein as a species within the instantly claimed genus of compounds that would have the functional characteristics of a SarR analog compound.

(Instant claim 29, 30) Additionally, Tegmark et al discloses a method that comprises the steps of"

Obtaining a Staphylococcal accessory regulatory R analog, wherein the analog was considered to be a SarA homolog named SarH1 (see summary section "Sar homologue 1) which functioned as a repressor molecule for hla promoter, the hla promoter controlling expression of alpha toxin and is a SarA promoter because upon SarA binding to the promoter to modulate expression of alpha toxin.

Contacting the SarR analog with an SarA promoter ("Four differentially regulated genes (hla, alpha-toxin; hld, RNAIII; spa, protein A; ssp, serine protease) were analyzed for binding of

potential regulatory proteins to the corresponding promoter DNA fragments linked to magnetic beads") ; and

Determining whether the SarA analog binds to a SarA promoter (Tegmark et al showed a protein of 29 kDa with a high degree of similarity to SarA to bind to the SarA promoter for hla the binding resulting in inhibited expression of a virulence factor. (see page 398, Summary "sarH1 has a strong repressive effect)

Tegmark et al inherently anticipates the instantly claimed invention as now claimed.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

14. Claims 29, 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Manna et al (1998) in light of evidence provided by Manna et al (2001).

15. Manna et al disclose the instantly claimed invention directed to:

(Instant claims 30-31) a compound that inherently would function as a Staphylococcal accessory regulatory (SarR) analog, wherein Manna et al isolated the SarR protein analog from S. aureus

and named it a 12 kDa protein based upon binding to the SarA P2 promoter, and suggested its biological function as a repressor.

The compound of Manna et al is not described based upon its biological function, ie. being an SarR analog of S.epidermidis and S.haemoyticus SarR proteins (evidence of difference in protein sequence, but still being an SarR protein is presented in Swiss-Prot accession number Q4L8F0 and Q5HLV6)

but the compound of Manna et al was shown to evidence SarR characteristics in light of evidence provided by Manna et al (2001, "Characteristization of sarR, a modulator of sar Expression in Staphylococcus aureus", abstract 12 kDa protein found to encode a 13.6 kDa protein).

(Instant claim 29) Additionally, Manna et al discloses a method that comprises the steps of"

Obtaining a Staphylococcal accessory regulatory R analog (heparin-Sepharose and DNA- specific columns, we partially purified a 12 kDa protein, abstract, page 3828)

Contacting the SarR analog with an SarA promoter ("we have localized a 34-bp sequence which seems to play a role in down-modulating P1 transcription"); and

Determining whether the SarA analog binds to a SarA promoter ("a 12 kDa protein, possibly a repressor, which binds to the promoter regions upstream of P2 and P1 and which also binds to the 34-bp sequence")

Manna et al inherently anticipates the instantly claimed invention as now claimed.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition

patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

16. Claims 28, 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Hurlburt et al (US Pat. 6,699,662 B1.

17. Hurlburt et al disclose the instantly claimed invention directed to:

(Instant claims 30-31) a compound that would function as a Staphylococcal accessory regulatory (SarR) analog that serves to inhibit SarA function and prevent the expression of Staphylococcal virulence factors (see Hurlburt et al col. 30, lines 26-34 and col. 35, lines 9-14).

One species of compound disclosed by Hurlburt et al is a mutant SarA mutant protein (see col. 30, lines 55-67) that will bind to SarA but prevent binding the agr promoter region, due to "disruption of subunit interactions" through forming a heterodimer (two proteins with different amino acid sequence or subunits that form a dimer).

A second species of SarR analog disclosed by Hurlburt et al is a prototype RNA inhibitor of SarA-agr promoter binding and has the sequence of "gly-TTTCTTAACTA-lys" , as well as an 18 mer "gly-TCCAATTTTTCTTAACTA-lys" (see col. 35, lines 15-57).

(Instant claims 28, 30 and 31) Hurlburt et al discloses a compound and method that comprises the steps of :

obtaining an SarA analog (see PNA inhibitors cols 35-36);

contacting the SarR analog with SarA (It is clear that the PNA molecule is able to out compete SarA for binding to the DNA and forms a protein-DNA complex" see Hurlburt et al col. 35, lines 50-53); and

determining where the analog forms a heterodimer ("forms a protein-DNA complex", a type of heterodimer ; see col. 36, lines 35-57 "heteroduplex" formed) which results in inhibition of expression of virulence determinants (see Hurlburt et al, col. 33, lines 66-67 and col. 34, lines 1-4).

Hurlburt et al inherently anticipates the instantly claimed invention as now claimed.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Conclusion

18. This is a Non-Final action.

19. The prior art considered pertinent to applicant's disclosure.

20. McNamara (PG-Pub 2003/0171563, Sep. 2003) is cited to show regulatory factors and cycle for expression of virulence factors (see Figure 1, SarR, SarA, agr) and also teach oxygen, carbon dioxide, osmolarity, glucose, pH, magnesium, heat, ethanol, detergents and antibiotics all serve as environmental compounds that effect virulence factor expression (see page 3, [0016]).

21. PG-Pub 20030148492 A1 is cited to show a composition that comprises an inhibitor of a winged-helix structure (see claims 8 and 15).

22. US Pat. 6656735 is cited to show a method of identifying winged-helix inhibitory agents (see claims 8-10).

23. Chien et al (1998) is cited to show a synthetic 45-bp fragment that comprises a 29 bp sequence that binds to SarA protein in band shift assay.

24. Tegmark et al (2000) teaches SarA to repress transcription of cna (collagen adhesin), spa and several other genes (see page 399, col. 1, paragraph 1).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 13, 2005

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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